



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	374190	REGKIRONA regdanvimab (rch) 960mg/16mL concentrate for solution for infusion
ARTG entry for	Medicine Registered (Provisional)	
Sponsor	Celltrion Healthcare Australia Pty Ltd	
Postal Address	Suite 13-03, 31 Market Street, Sydney, NSW, 2000 Australia	
ARTG Start Date	6/12/2021	
Product Category	Medicine	
Status	Active	
Approval Area	Drug Safety Evaluation Branch	



Medicine under additional monitoring

Conditions

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Products

1 . REGKIRONA regdanvimab (rch) 960mg/16mL concentrate for solution for infusion

Product Type	Single Medicine Product	Effective Date	6/12/2021
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Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

Provisionally Registered Indications

REGKIRONA has provisional approval for the treatment of adults with coronavirus disease 2019 (COVID-19) who do not require supplemental oxygen and are at increased risk of progressing to severe COVID-19 (see Section 5.1 PHARMACODYNAMIC PROPERTIES, Clinical Trials). The decision has been made on the basis of short term efficacy and safety data. Continued approval of this indication depends on the evidence of longer term efficacy and safety from assessment.

Provisionally Registered Conditions

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

This product is included in the Black Triangle Scheme

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Glass Type I Clear	12 Months	Store at 2 to 8 degrees Celsius	Not recorded	Do not Freeze

Pack Size/Poison information

Pack Size	Poison Schedule
1 vial	(S4) Prescription Only Medicine

Components

1 . REGKIRONA regdanvimab (rch) 960mg/16mL concentrate for solution for infusion

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Dosage Form Injection, concentrated
Route of Administration Intravenous Infusion
Visual Identification REGKIRONA is a sterile, clear to opalescent and colourless to pale yellow solution.

Active Ingredients

regdanvimab **60 mg/mL**

Other Ingredients (Excipients)

arginine hydrochloride
histidine hydrochloride monohydrate
histidine
polysorbate 80
water for injections

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